

REMARKS

Claims 1-21 are pending herein. By this Amendment, Claims 1 and 13 are amended and new Claims 14-21 are added. In addition, withdrawn Claims 7-12 are amended.

Support for the claim amendments and new claims is found in the specification at, *inter alia*, paragraphs [0013], [0015], [0026]-[0027], [0036], [0038], [0047]-[0053], [0055], and [0069]. No new matter is added by this Amendment.

I. SUMMARY OF PERSONAL EXAMINER INTERVIEW

Applicant thanks Examiner Lin for the courtesies extended to his representative at the February 22, 2007 personal examiner interview. Applicant's separate record of the interview is set forth in the foregoing amendments and the following remarks.

At the interview, Applicant's representative discussed claim amendments to overcome the formal rejections. Further, Applicant's representative discussed the claim amendments directed to determining whether sperm parameters of the rodents from a contaminated site exceeds one or more sperm parameter benchmarks (i.e., thresholds for effect), thereby indicating if the rodents from the contaminated site have impaired reproductive capability. See, for example, paragraphs [0010], [0048], [0082] and Table 12. Applicant's representative argued that this is feature is not taught or suggested in the art of record.

II. RESTRICTION/ELECTION REQUIREMENT

Applicants thank Examiner Lin for joining Group II (Claim 13) with elected Group II (Claims 1-12). In view of the election of species A (measuring sperm count), Claims 7-12 are withdrawn from consideration. As discussed at the interview, Claims 7-12 are currently amended in view of possible rejoinder.

III. FORMAL MATTERS

Claims 1-6 and 13 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Claims 1 and 13 are amended to clarify that the “receptors” are animals. In addition, Claim 13 is amended to clarify that the “burning pads” are former burning ground sites. Claim 1 is further amended to recite determining whether the at least one result of the first sperm analysis exceeds one or more sperm parameter benchmarks, thereby indicating if the rodents from the contaminated site have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site. Claim 13 is similarly amended. Thus, Claims 1 and 13 do not fail to recite essential steps. Claim 13 is also amended to delete the terms “high” and “low”.

The scope of Claims 1-6 and 13 would be reasonably ascertainable to one of ordinary skill in the art when read in light of the specification and drawings, thereby satisfying the requirements of 35 U.S.C. 112, second paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. REJECTIONS UNDER 35 U.S.C. 102(b) AND 103(a)

Claims 1-3 and 6 were rejected under 35 U.S.C. 102(b) as anticipated by Ieradi et al., *Genetic Damage in Urban Mice Exposed to Traffic Pollution*, Environmental Pollution, Vol. 92, No. 3, pp. 323-28 (1996). This rejection is respectfully traversed.

Ieradi et al. discloses collecting rodents from three areas in Rome exposed to different traffic flows to ascertain a possible correlation between genetic damage and heavy metal concentration (Abstract). A statistically significant increase in the frequency of abnormal sperm cells was obtained in animals collected in sites with high traffic flows. A sperm abnormality assay was carried out (page 324, left column).

Although Ieradi et al. discloses sperm abnormalities of wild rodents and correlates abnormal sperm count frequencies to contents of cadmium and lead in the kidney, there is no disclosure of determining whether a first sperm analysis exceeds one

or more sperm parameter benchmarks, thereby indicating if the rodents from the contaminated site have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site.

For example, as discussed at the interview, it may be determined that the rodents trapped at the contaminated site may have a lesser sperm count (for example, a reduction of 16.7%). Numerous studies indicate that many species of rodents are robustly fertile, and that sperm count needs to be reduced approximately 80% or more (sperm parameter benchmark) before reproductive success is compromised. If a study reveals that sperm count in rodents trapped at the contaminated site is only reduced by 40% when compared with the rodents of the uncontaminated reference location, a sperm parameter benchmark will not have been exceeded, and it cannot be determined that reproductive success will be compromised in these animals.

Thus, Ieradi et al. does not disclose determining whether at least one result of the first sperm analysis exceeds one or more sperm parameter benchmarks, thereby indicating if the rodents from the contaminated site have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site, as recited in Claim 1. Ieradi does not disclose each and every element of the claimed methods. Thus, Claims 1-3 and 6 are not anticipated. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1, 4-5, and 13 were rejected under 35 U.S.C. 103(a) as obvious over Ieradi et al. and in view of Sharma et al., *Reversible Effects of Mercuric Chloride on Reproductive Organs of the Male Mouse*, Reproductive Toxicology, Vol. 10, No. 2, pp. 153-59 (1996). This rejection is respectfully traversed.

As noted, Ieradi et al. does not teach or suggest determining whether at least one result of the first sperm analysis exceeds one or more sperm parameter benchmarks, thereby indicating if the rodents from the contaminated site have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site, as recited in Claim 1. Likewise, Ieradi et al. does not teach or suggest determining

if the results of assessment of the rodents from animal study site exceeds one or more sperm parameter benchmarks, thereby indicating if the rodents from the animal study sites have impaired reproductive capability and assessing the ecological risk to animals at the animal study sites, as recited in Claim 13. Ieradi et al. also does not teach or suggest measuring sperm count (Claim 4) or measuring sperm motility (Claim 5).

Sharma et al. does not overcome the deficiencies of Ieradi et al. Sharma et al. discloses the effects of oral administration of mercuric chloride (HgCl_2) on mouse testis, vas deferens, epididymis, and cauda epididymal sperm. Testis, vas deferens, and epididymis functions were evaluated with respect to sperm count, sperm motility, and viability (Abstract).

Sharma et al. merely discloses absolute toxic effects of mercury. There is no teaching or suggesting of assessing ecological risk of a contaminated site using reduced reproductive success as a toxicological endpoint. Thus, although sperm damage is shown in Sharma et al., there is no teaching or suggestion of relating the amount of damage to reproductive success or ecological risk.

Sharma et al. does not teach or suggest determining whether at least one result of the first sperm analysis exceeds one or more sperm parameter benchmarks, thereby indicating if the rodents from the contaminated site have impaired reproductive capability and assessing the ecological risk to animals at the contaminated site, as recited in Claim 1. Sharma et al. also does not teach or suggest determining if the results of assessment of the rodents from animal study site exceeds one or more sperm parameter benchmarks, thereby indicating if the rodents from the animal study sites have impaired reproductive capability and assessing the ecological risk to animals at the animal study sites, as recited in Claim 13.

Thus, it would not have been obvious for one of ordinary skill in the art to practice the claimed methods in view of the combined teachings of Ieradi et al. and Sharma et al. Reconsideration and withdrawal of the rejection are respectfully requested.

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V. CONCLUSION

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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